

DEC 09 2005

This report is required by law (7 USC 2143). Failure to report according to the regulations can

See attached form for additional information

Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER 23-R-0023
CUSTOMER NUMBER 319

FORM APPROVED
DATE 10/1/03

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

University Of Pennsylvania
(b)(6), (b)(7)c
(b)(2)High, (b)(7)f
Mail Code 6303
Philadelphia, PA 19104
Telephone: (215)-898-7236

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	456	5	551	0	556
5. Cats	0	0	256	0	256
6. Guinea Pigs	0	14	274	7	295
7. Hamsters	0	0	2	0	2
8. Rabbits	0	27	214	0	241
9. Non-human Primate	0	2	49	0	51
10. Sheep	0	5	135	0	140
11. Pigs	0	483	521	0	1004
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

b6,b7c

11/30/2005

RAW

FORM APPROVED
OMB NO 0579-0036

T: (215) 898-7236

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility
- 2) Each principal investigator has considered alternatives to painful procedures
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

11/30/2005

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 23-R-0023

2. Number 7 of animals used in this study.

3. Species (common name) Guinea pigs of animals used in this study.

4. Explain the procedure producing pain and/or distress.

This experiment determines the effectiveness of new antibiotics in the treatment of Legionella disease. Guinea pigs are infected via intratracheal injection with *L. pneumophila*. One day after infection, they are treated with antibiotics currently used in treatment, saline solution alone, or the test antibiotic. The treatments are given for 2 to 5 days and the animals observed for a subsequent 5-day period. Efficacy of the test antibiotic is compared with the currently used antibiotics.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below.)

No analgesia is given immediately postsurgical period, or later, for several reasons:

- a) There is no observable animal distress in the immediate postoperative period. The animals awaken from anesthesia within a few hours, then are normally active, eating and drinking normally.
- b) There is little observable evidence of distress in ill animals, other than tachypnea, as the animals tend to become lethargic as they become ill.
- c) The stress of injections may affect survival.
- d) Any depression of respirations by analgesic agents could be fatal in these animals with pneumonia.
- e) Since death is not used as an endpoint, clinical observation of the degree of illness, as well as weight and temperature, are used as indices of the degree of pneumonia. It is possible that analgesia could obscure important clinical signs, or even that it could induce lethargy – which is normally a good marker of severe pneumonia.

Unfortunately, there are no reliable subjective or objective clinical findings that can predict the likelihood of death before a point of severe illness in the animals. Therefore, it is necessary to use very severe illness as an endpoint, rather than an earlier time point. Some journal reviewers have even criticized the present severe illness endpoint, demanding an endpoint of death as being more objective. I am certain that the reliability of the animal data would be justifiably attacked, were I to use an earlier time point than my present one.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g. APHIS, 9 CFR 113.102):

Agency _____ CFR _____